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PATENT Attorney Docket No.: SALK2350

(Foley No. 088802.5351)

e.g., x-ray diffraction, that can be used to generate a three-dimensional model of a chimeric protein; in methods for identifying compounds that have particular characteristics and properties, including but not limited to the property of being a ligand of a chimeric protein of the invention; and the like.

Restriction and Election

The restriction of claims 1-60 under 35 U.S.C. §121 as allegedly being drawn to 7 distinct inventions (groups) is respectfully traversed. Applicants respectfully disagree with the assertion in the Office Action that inventions I-VII are allegedly distinct from each other (page 3, lines 3-22). It is respectfully submitted that all of the groups are related to the chimeric proteins of the invention and various uses thereof.

With all due respect, the Examiner has apparently failed to consider the common thread weaving through all the claims, i.e., a chimeric protein comprising at least two functional protein units, wherein each functional unit comprises a dimerization domain of a member of the steroid/thyroid hormone nuclear receptor superfamily. All the compositions and methods of the claims flow from this concept. Accordingly, a prior art search of the claims of one group would necessarily require a search of the claims of the other groups. Thus, no conservation of PTO resources would be realized if the restriction requirement as asserted is maintained. Therefore, restriction of claims 1-60 is clearly inappropriate.

Applicants further disagree with the assertion in the Office Action that Groups I and III-V, although acknowledged to be related as product and process of use, are nonetheless distinct. The Examiner's assertion that "the product as claimed can be used in a materially different process of using that product" (page 3, lines 12-13) is of no benefit. Group I is drawn to chimeric proteins of the invention, and Groups III-V encompass various methods of

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using the chimeric proteins. The example of a "materially different process of using" the chimeric proteins of group I presented in the Office Action involves the fact that "the protein of invention I can be used for the production of antibodies" (page 3, lines 14-15). It is respectfully submitted that the use of chimeric proteins of the invention to make antibodies is not a "materially different process of using" the proteins under the aegis of MPEP §806.05(h). Rather, the ability of the protein to elicit an immune response, in which antibodies are generated, is a characteristic of proteins. Due to the remarkable abilities of the immune system, any protein can be "used" to generate antibodies. Thus, according to the reasoning set forth in the Office Action, every use of any protein (i.e., any protein that can be used to generate antibodies) is distinct and independent from any other use of that protein. That is, under the rationale of the argument set forth in the Office Action, any use of any protein may be treated as a distinct invention that is placed in a different group than the group that contains the protein. It is respectfully submitted that this harsh result is inappropriate.

Applicants further disagree with the assertion in the Office Action that Group II is unrelated to Groups III–V and VII (page 3, line 16) because "the different inventions are not disclosed as capable of use together" (page 3, line 19). This assertion ignores the content of the claims in these groups. Group II encompasses claims drawn to a "polynucleotide that encodes a chimeric protein" of the invention and host cells therefor (see, e.g., claims 23-25). Group III includes claim 27 (page 71, lines 1-2), which is drawn to a method in which "the chimeric protein is encoded by a DNA construct," i.e., a DNA construct that comprises a "polynucleotide that encodes a chimeric protein" as set forth in claim 23 of Group II. Similarly, claims 44 and 46 (page 73, lines 8-9 and lines 18-19), which are included in Group IIII (sic., IV), are drawn to methods in which "the chimeric protein is encoded by an inducible DNA construct," i.e., an inducible DNA construct that comprises a "polynucleotide that encodes a chimeric protein" according to claim 23 of group II. The content of the claims thus clearly indicates that the methods of Groups III and IIII (sic., IV) make use of DNA constructs

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that comprise the polynucleotides of Group II, and are thus "disclosed as capable of use together". As they are clearly related, Groups II-IIII (sic., IV) could readily be considered in the same application.

In any event, it is respectfully submitted that the claims have been unduly restricted into an excessive number of Groups. Several of the groups are drawn to highly related methods. For example, Groups III, IIII (sic., IV) and V are all stated to be drawn to "a method for modulating an exogenous gene" (page 2, lines 16-19 and 21-22). Contrary to the assertion in the Office Action (page 3, lines 7-9), the claimed methods make use of similar, in some instances identical, starting materials; have similar and in some instances identical, process steps; and are all used for the same purpose, i.e., modulation of gene expression. Thus, Groups III-V clearly all relate to the use of the chimeric proteins of the invention to modulate gene expression. Certainly, these groups could readily be considered in the same application.

Applicants also note that the Office Action provides no rationale for treating the claims of Group VI as distinct from those of Groups III, IV, V or VII. As no prima facie case of unrelatedness has been presented, these claims should not be treated as defining an independent invention. At a minimum, the combinations of Groups III and VI; IV and VI; V and VI; and VI and VII should each be considered in the same application. As Groups III-V and VII all share a common thread with Group VI, surely Groups III-VII can be readily considered in the same application.

It is respectfully submitted that no justification has been provided for restricting the claims into such an unreasonable number of groups. Accordingly, reconsideration and withdrawal of the restriction requirement under 35 U.S.C. §121 are respectfully requested.

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In the alternative, re-organization of the claims into fewer groups is respectfully requested. For example, as noted above, Groups III-VII, III-V, or II-IIII (sic., IV), could readily be processed in one application.

In order to be fully responsive, Applicants elect the Group I claims (i.e., claims 1–22 and 52-54, drawn to chimeric proteins of the invention) with traverse. Claims 23-51, and 55-60 are retained herein pending final disposition of the elected claims.

Sequence Listing

The Office Action dated May 8, 2001, included a Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Responsive to the Notice, a Sequence Listing and all associated documentation is being submitted under separate cover.

In view of the above remarks, prompt and favorable action on all claims are respectfully requested. If any questions remain after consideration of this response, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: $\frac{6}{8}$

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